COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 27-X-2006
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NOT FOR PUBLICATION

COMMISSION DECISION

of 27-X-2006

on the transfer of the marketing authorisation granted by Decision C(2004)3160 for "Ariclaim - duloxetine hydrochloride", a medicinal product for human use

(ONLY THE GERMAN, DUTCH TEXT IS AUTHENTIC)

COMMISSION DECISION

of 27-X-2006

on the transfer of the marketing authorisation granted by Decision C(2004)3160 for "Ariclaim - duloxetine hydrochloride", a medicinal product for human use

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1],

Having regard to Commission Regulation (EC) No 2141/96 of 7 November 1996[2] concerning the examination of an application for the transfer of a marketing authorisation for a medicinal product falling within the scope of Council Regulation (EEC) No 2309/93, and in particular Article 6 thereof,

Having regard to the application submitted by Boehringer Ingelheim International GmbH on 5 September 2006 under Article 3 of Regulation (EC) No 2141/96,

Whereas:

(1) The medicinal product "Ariclaim - duloxetine hydrochloride", entered in the Community register of medicinal products under the numbers EU/1/04/283/001-007 and authorised by Commission Decision C(2004)3160 of 11 August 2004, remains in compliance with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3].

(2) A change of holder of the marketing authorisation for which the transfer application is made is a change of an administrative nature, which does not affect the scientific characteristics of the medicinal product already authorised.

[1] OJ L 136, 30.4.2004, p. 1
[2] OJ L 286, 8.11.1996, p. 6.
[3] OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p.34).

(3) It is appropriate to set the date by which all the operations resulting from the transfer of the marketing authorisation must be completed.

(4) The European Medicines Agency has given a favourable opinion,

(5) For the sake of clarity and transparency, it is advisable, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C (2004)3160 should therefore be replaced,

HAS ADOPTED THIS DECISION:

Article 1

The marketing autorisation granted by Commission Decision C(2004)3160 of 11 August 2004 for the medicinal product "Ariclaim - duloxetine hydrochloride" entered in the Community register of medicinal products under No(s) EU/1/04/283/001-007, is hereby transferred from Boehringer Ingelheim International GmbH to Eli Lilly Nederland B.V..

Article 2

Decision C(2004)3160 is amended as follows:

1) Annex I is replaced by the text set out in Annex I to this Decision;

2) Annex III is replaced by the text set out in Annex III to this Decision.

Article 3

1) The transfer referred to in Article 1 shall be authorised from the date of notification of this Decision.

2) All the operations resulting from this transfer must be completed by 6 December 2006 at the latest.

Article 4

This Decision is addressed to:
1. Eli Lilly Nederland B.V., Grootslag 1-5, 3991 RA Houten, Nederland
and
2. Boehringer Ingelheim International GmbH, Binger Strasse 173, D-55216 Ingelheim am Rhein, Deutschland.

Done at Brussels, 27-X-2006

For the Commission
Heinz ZOUREK
Director-General